

**REPLY DECLARATION OF CHRISTOPHER J. MCDONALD
IN FURTHER SUPPORT OF END-PAYOR PLAINTIFFS'
MOTION FOR CLASS CERTIFICATION [PUBLIC VERSION]**

Exhibit 66

Chapter 6

Evolution of the Management of U.S. Health Care: Managing Costs to Care Management

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Introduction and Background

The financing and delivery of health care services in the United States has been dramatically transformed over the past 30 years since President Nixon signed the HMO Act in 1973. Managed care existed prior to the 1973, but the HMO Act provided federal funding and encouraged the eventual proliferation of *health maintenance organizations* (HMOs), the initial form of modern managed care. Traditional fee-for-service medicine began its slow death, and the practice of medicine and pharmacy was immutably and profoundly altered forever. Managed care grew because it promised to satisfy two growing societal needs. First, managed care offered to improve the quality of care by encouraging preventive or preemptive care, as well as providing treatment care, and, second, managed care promised to contain a steadily rising and unsustainable health

care cost trend. Table 6-1 shows costs by health care delivery segment, percent of total costs, and annual trend rates.

Managed care will be compared to indemnity insurance more fully below, but the essential difference is that managed care offers a prepaid membership with a defined panel of contracted health care providers, compared with an indemnity insurance plan that allows patients to seek care from any community provider, who was then reimbursed on a fee-for-service basis. While managed care began to flourish in many regions in the 1970s, its actual genesis began earlier in the 20th century.¹ The Western Clinic in Tacoma, Washington, began offering health care services for lumber mill employees for a defined monthly premium. A health care cooperative for rural farmers was established in Oklahoma City, Oklahoma, in 1929. Kaiser

Table 6-1

Total Personal Health Care Expenditures by Type of Service (1960–2000)

Type of Service	1960			1990			1999			2000	
	Amount	Percent	Trend*	Amount	Percent	Trend*	Amount	Percent	Trend*	Amount	Percent
Personal Health Care	\$23.4	100.0%	10.0%	\$609.4	100.0%	6.0%	\$1,062.1	100.0%	6%	\$1,130.4	100.0%
Hospital Care	\$9.2	39.3%	10.0%	\$253.9	41.7%	5.0%	\$392.2	36.9%	5%	\$412.1	36.5%
Physician/Clinical Services	\$5.4	23.1%	10.0%	\$157.5	25.8%	6.0%	\$270.2	25.4%	6%	\$286.4	25.3%
Dental Services	\$2.0	8.5%	9.0%	\$31.5	5.2%	7.0%	\$56.4	5.3%	6%	\$60.0	5.3%
Other Professional Care	\$0.4	1.7%	12.0%	\$18.2	3.0%	8.0%	\$36.7	3.5%	6%	\$39.0	3.5%
Home Health Care	\$0.1	0.4%	16.0%	\$12.6	2.1%	10.0%	\$32.3	3.0%	<1%	\$32.4	2.9%
Prescription Drugs	\$2.7	11.5%	10.0%	\$40.3	6.6%	12.0%	\$103.9	9.8%	17.0%	\$121.8	10.8%
Non-Durable Medical Products	\$1.6	6.8%	8.0%	\$22.5	3.7%	3.0%	\$30.4	2.9%	3.0%	\$31.2	2.8%
Durable Medical Equipment	\$0.7	3.0%	9.0%	\$10.6	1.7%	6.0%	\$17.6	1.7%	5.0%	\$18.5	1.6%
Nursing Home Care	\$0.7	3.4%	13.0%	\$52.7	8.6%	6.0%	\$89.3	8.4%	3.0%	\$92.2	8.2%
Other Personal Health Care	\$0.6	2.6%	11.0%	\$9.60	1.6%	14.0%	\$33.7	3.2%	9.0%	\$36.7	3.2%

Source: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group. Available at: <http://www.cms.hhs.gov/review/supp/2001/table4.pdf>.

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Foundation Health Plans began in 1937 to provide health care for Kaiser construction workers and shipbuilders. Similar cooperative *group health plans* developed elsewhere, including Minnesota and Seattle.

Today, health insurance in the United States is commonly offered by employers as an employee benefit and is partially paid by employers. Managed health care benefit plans purchased by private businesses are described as *commercial plans*. Large corporations with adequate financial reserves may qualify to create its own *self-insured plan* that will be developed and customized on its behalf by a health plan for its employees. Self-insured plans are exempt from certain regulations governing commercial health care benefits. Pharmacy benefits are included in over 90% of commercial health plans. All health care in the U.S. is *managed* except the dwindling amount of fee-for-service cash business. Over 90% of all prescription transactions in the U.S. is reimbursed by a private commercial or public (e.g., Medicaid or Medicare) prescription drug program.

Government-sponsored health plans include health and pharmacy benefits for selected populations. Medicaid provides comprehensive care for beneficiaries usually under age 65 and of very low income; Medicare provides health and pharmacy benefits (as of January 1, 2006) for beneficiaries age 65 and over; and the Veterans Administration and Department of Defense plans offer benefits for active and retiree armed forces members and certain government employees. Both private employer groups and government purchasers of health care are known as *payers* because they purchase health care benefits on behalf of their members or beneficiaries. The most broadly sweeping pharmacy benefit changes have recently occurred in Medicare. The Medicare Modernization Act (MMA) signed by President Bush in 2003 provides for an outpatient pharmacy benefit for Medicare members under Part D beginning January 2006. The impact of the MMA on pharmacy benefits for Medicare recipients will be discussed in greater detail elsewhere.

Elements of Managed Care

The essence of managed care is to manage any and all products and services in the health care delivery system. There are two essential aspects of every activity in health care delivery that must be managed: the unit cost of each product or service, and the utilization rate of each product or service. Therefore, managed care attempts to obtain a discount contract from all provi-

ders of care, including physicians, dentists, hospitals, long-term care facilities, pharmacies (community, mail service, and specialty pharmacy), chiropractors, and others, as well as from all providers products including pharmaceuticals companies, durable and disposable medical equipment vendors, home health care, diagnostic instruments, and any other product used in health care delivery.

While the discounted contracts for all health care products and services control the supply side of resource costs, equally important is controlling the demand for services. Physicians (and other health care professionals with prescriptive authority) are ultimately responsible for ordering the use of health care resources. As a result, health plan participation contracts with physicians require them to use discounted health care resources (e.g., referring patients only to contracted specialists, admitting only hospitals under contract, and prescribing drugs on the formulary). Physicians may have financial incentives or penalties for inefficiently using services or ordering cost-ineffective treatments if not clinically justified.

In addition to physicians, patients (health plan members) are also responsible for causing inefficient use of resources by seeking unnecessary care and requesting unneeded prescriptions and inappropriate use of resources (e.g., visiting the emergency department for trivial illnesses). Therefore, managed care and payers typically require members to share in the plan's financial responsibility by paying part of the health care premium and paying a *user fee* (copayment or coinsurance) when they access health care services. In summary, managed care attempts to share the financial risk with any and all entities that can influence the supply and demand, the cost and utilization, or all health care resources.

Health plans must provide a system that encourages the provision of high quality, cost-effective health care while also controlling health care costs. State courts have held that health plans do not *practice* medicine but provide a financing and delivery system in which physicians practice medicine and remain ultimately responsible for ordering or causing all health care to be provided to eligible health plan members. There is often tension between the health plan that is trying to manage the cost and utilization rate of all health care services and the physician and patient who may request more services or more expensive services that is recommended by the plan. For that reason, all health plans provide an appeal process to review any patient

situation in which services are denied and physicians or patients challenge the denial. Therefore, to be successful in the long-term, health plans must develop a benefit design and delivery system structure that rewards physicians to order cost-effective products and services that balance short-term costs and outcomes with longer-term costs and outcomes.

Managed care generally includes the following elements in an attempt to provide cost-effective and high quality health care products:

Defined Inclusion and Exclusion of Benefits

Managed care does not offer unlimited products and services but by contract must specify which benefits are covered and which are excluded. For example, excluded benefits include investigational and experimental medications and procedures. The managed care contract will also specify the monthly premium as well as any copayments or coinsurance requirements. The drug formulary describes drugs eligible for reimbursement as well as prescription limitations (e.g., quantity limits or prior authorization).

Prepaid, Membership Health Care Services

Opposed to paying specifically for and only when health care services are obtained. Members of a managed care system pay a fixed monthly premium regardless if they use services or not. In addition, managed care members often pay a small, fixed copayment or percent coinsurance, which is essentially a user fee, when they actually do utilize covered products and services.

Defined Provider and Vender Network

Managed care organizations contract with specific health care facilities, health providers, and vendors to obtain all products and services at discounts for health plan members. Discounted contracts for all products and services are obtained in exchange for the increase in utilization as a result of the health plan encouraging, or requiring, members to use the contracted providers. Some plans will allow access to noncontracted *out-of-network* providers at a higher member copayment or coinsurance cost. To obtain discounted prescription benefits, members must use contracted community and mail service pharmacies for most drugs or contracted specialty pharmacies for certain injectables.

Preventive and Quality Management Services

The original HMO Act of 1973 provided for preventive care. Health plans typically offer preventive health

care screening, encourage annual physical exams, and have specific care management or case management programs to manage high cost and high prevalence diseases (e.g., diabetes, obesity, hypertension, dyslipidemia, organ transplants, depression). Drug utilization review, online or telephone drug information, and medication adherence monitoring are common pharmacy benefit quality assurance programs. The National Committee on Quality Assurance (NCQA) accredits achievement of defined health plan quality measures, similar to the JCAHO accreditation of in-patient facilities. Payers often consider the NCQA accreditation status when selecting a health plan.

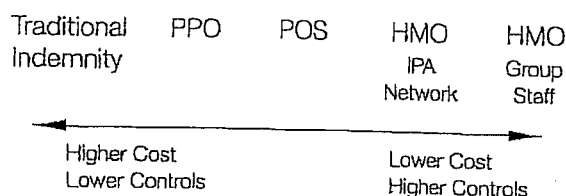
Types of Managed Care Organizations

In 1973, the term *managed care* signified a health maintenance organization (HMO). This term, allegedly created by Dr. Paul Ellwood, a Minnesota physician and health care advisor to national health care policymakers, promoted the preventive medicine benefits of an HMO with prepaid health care. Early HMOs were typical of a highly controlled staff model or group model plan, such as Kaiser-Permanente Health Plan, which owned medical facilities and employed health care providers. To obtain care, members had to visit the owned medical centers, hospitals, and pharmacies, and were treated by employed physicians. In the late 1970s and early 1980s, a different type of less structured HMO developed. The less controlled network model and independent practice association (IPA) model plans began to flourish. Network model plans and IPAs owned no facilities and employed no physicians but rather contracted with private practice, community-based hospitals, physician groups, and pharmacies to provide services. However, there was a trade-off among model types between the ability to control costs or offer richer benefits. High control such as a staff or group model HMOs (e.g., Kaiser-Permanente Health Plan) were more effective in controlling costs but offered less member freedom of choice of services and community providers. Conversely, less controlled HMOs, such as network and IPA models (e.g., United HealthCare), offered more member freedom of choice, but that choice came at a slightly higher cost.

In an attempt to provide more options to employer groups and members, managed care organizations have developed more plan options, some of which provide even greater freedom of choice. A preferred provider

organization (PPO) provides an expanded network of community providers and greater member choice. The point of service (POS) plan combines the benefits of a controlled HMO and a less controlled PPO. In a POS option, members can decide if they would stay within the contracted network (for a lower cost) or go to a noncontracted provider (at a higher cost). We use the term *health plan* or *managed care organization* (MCO) as generic terms to refer to a managed care organization that provides comprehensive inpatient medical, outpatient medical, and prescription drug benefits. At the end of 2003, there were approximately 72 million members in HMOs and 112 million members in PPOs.² We use the term *pharmacy benefit managers* (PBMs) to refer to companies that specialize in providing only prescription drugs benefits. Figure 6-1 provides a graphical interpretation of the balance of benefit freedom and cost control.

Figure 6-1
Comparison of Different MCO
Types, Level of Control, and
Relative Cost



Source: R. Navarro, 2005.

Managed care is neither a singular process nor a static event. Health plan medical and pharmacy benefits, structure, and operations are highly variable based on geographic region, local market competition, state coverage requirements, political considerations, and employer and member demands. And, health plans will evolve over time in response to the same influences and to increase appeal to its customers.

Flow of Money through Managed Care

Managed care is a highly regulated and contracted delivery system. The payers and purchasers of health care (e.g., employer groups, government), health plan members, providers of care (e.g., physicians, pharmacies, hospitals, long-term care facilities), and vendors

(e.g., DME companies, home health care agencies) all have a contractual relationship with the health care plans. All of these stakeholders are financially linked or at risk in some way to encourage observance with the cost-containment policies of the health plan.

Purchasers of care (employer groups, government) pay premiums to health plans for health benefits and to PBMs for prescription benefits. Health plans pay hospitals, physicians, and pharmacies a discounted reimbursement for services provided. Pharmacies purchase drugs through wholesalers or directly from pharmaceutical companies. Pharmaceutical companies provide discounts or pay rebates to health plans or PBMs to enhance the cost-effectiveness and formulary position of their products. Patients pay a copayment or coinsurance whenever they access the health care system. In exchange for having access to health plan members, providers and vendors under contract agree to provide products and services for a defined discount. Figure 6-2 demonstrates the contractual relationships and flow of money throughout the delivery system.

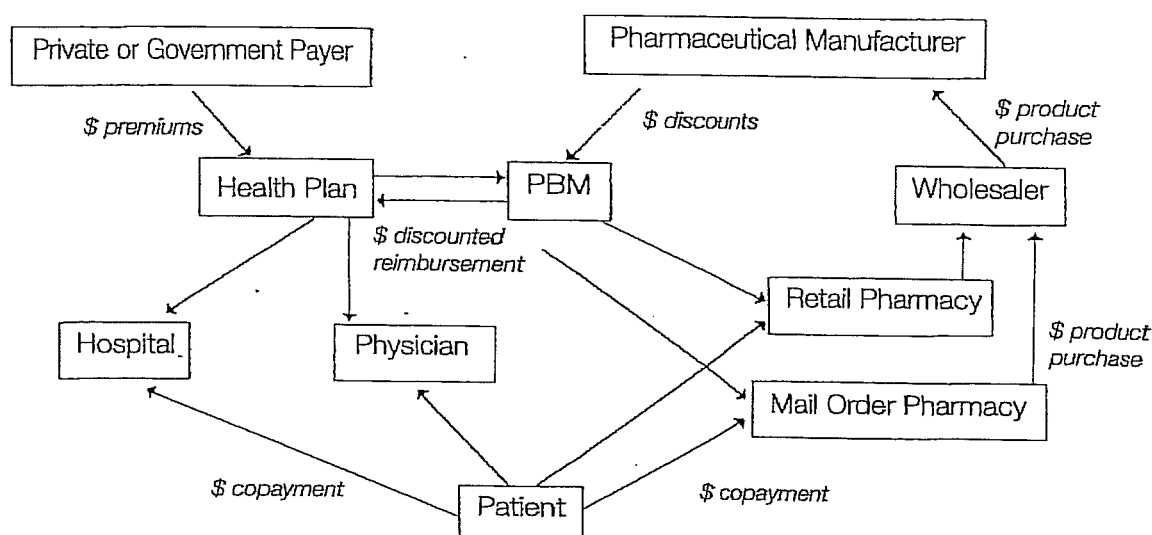
When examining health plan operations, one must understand how health care providers are reimbursed for their services. Physicians employed by a closed-model plan (e.g., staff or group models) are usually salaried and may receive a bonus linked to plan performance or their own efficiency. Community physicians participating with open-model plan (e.g., IPA or network health models) are generally reimbursed through either a capitation or a discounted fee-for-service arrangement and also may receive a financial incentive for efficient performance. Physicians are usually not at financial risk for the cost of the drugs they prescribe, although there can be geographical and plan-specific variances.

Physician Capitation Reimbursement

Through capitation, a physician (or medical group) receives a fixed monthly fee for providing covered services based upon the number of enrolled members that are assigned to the physician or medical group. The physician or medical group receives the same monthly fee per assigned member regardless of how many times the members may see the physician or how many covered outpatient services the physician provides. Through capitation, the HMO transfers a portion of the financial risk to the physician. Theoretically, this will serve as an incentive to the physician to provide only necessary and cost-effective care. The

Figure 6-2

Flow of Money through a Managed Care Delivery System



Source: R. Navarro, 2005.

capitated physician is expected to include a full range of services that often include all outpatient visits, preventive care, diagnostic tests, laboratory, and other office-based services. Medical groups that receive a capitation rate that includes drug costs usually create their own formulary, or preferred drug list, in an attempt to manage their drug costs.

Physician Discounted Fee-For-Service (FFS) Reimbursement

Under a discounted FFS reimbursement system, physicians receive payment only when they provide covered services to health plan members. However, their reimbursement is discounted from usual and customary (U&C) payment rates. This provides a mechanism to reduce costs per service. Also, physicians generally receive only a portion of the reimbursement for services rendered (e.g., 80%). The remaining 20% is withheld and maintained in a reserve to be paid out at the end of the year if certain cost and utilization performance objectives are met. High-risk outlier patients (e.g., patients with transplants or AIDS) that may bias the financial performance are eliminated. Inefficient (most costly) physicians may not receive their financial reserve. Physicians that are *average* performers receive their reserve payment. Physicians that are the most

efficient will receive a bonus (essentially the withhold that is not returned to the least efficient physicians).

Hospitals are reimbursed on a per diem, DRG, other fixed-fee basis, or discounted FFS arrangement depending on the service and procedure provided. The cost of inpatient drugs are typically included in the overall hospital fee and are not reimbursed separately (certain expensive drugs may be carved-out and billed separately by mutual agreement). As a result, health plans generally do not have any role or interest in determining inpatient drug formularies. Exceptions include those health plans that own hospitals (e.g., Kaiser-Permanente), where outpatient and inpatient drug purchasing may be coordinated. Hospital reimbursement practices are addressed elsewhere in this book.

Managed Pharmacy Benefits

Outpatient pharmacy benefits are an important component of comprehensive health care benefits offered by managed care organizations and purchased by both commercial and government payers. As of January 2006, Medicare, Medicaid, and over 90% of commercial health plan members will have access to outpatient prescription drug benefits. Arguably, drugs are the most cost-effective form of disease prevention and treat-

ment for many highly prevalent and diseases, including cardiovascular disease, diabetes, migraine headache, asthma, depression, and GERD.

Pharmacists managing prescription drug benefits must provide high quality pharmacy benefits while managing program costs. The quest to manage costs, rather than merely minimize costs, remains the challenge. As pharmacy program costs continue to escalate at an annual trend rate of approximately 20%, it is tempting to merely restrict expensive drugs or increase the patient copayment tier at an equal rate. However, simply focusing on cost-minimization is myopic and ultimately cost-ineffective. Figure 6-3 shows the rate of growth of hospital, physician, and pharmacy costs over the past decade.

Health plan administrators, as well as commercial and government payers, often consider pharmacy benefits only as a cost center, and do not appreciate the value a well managed pharmacy benefit can bring to clinical, economic, and humanistic outcomes. Health

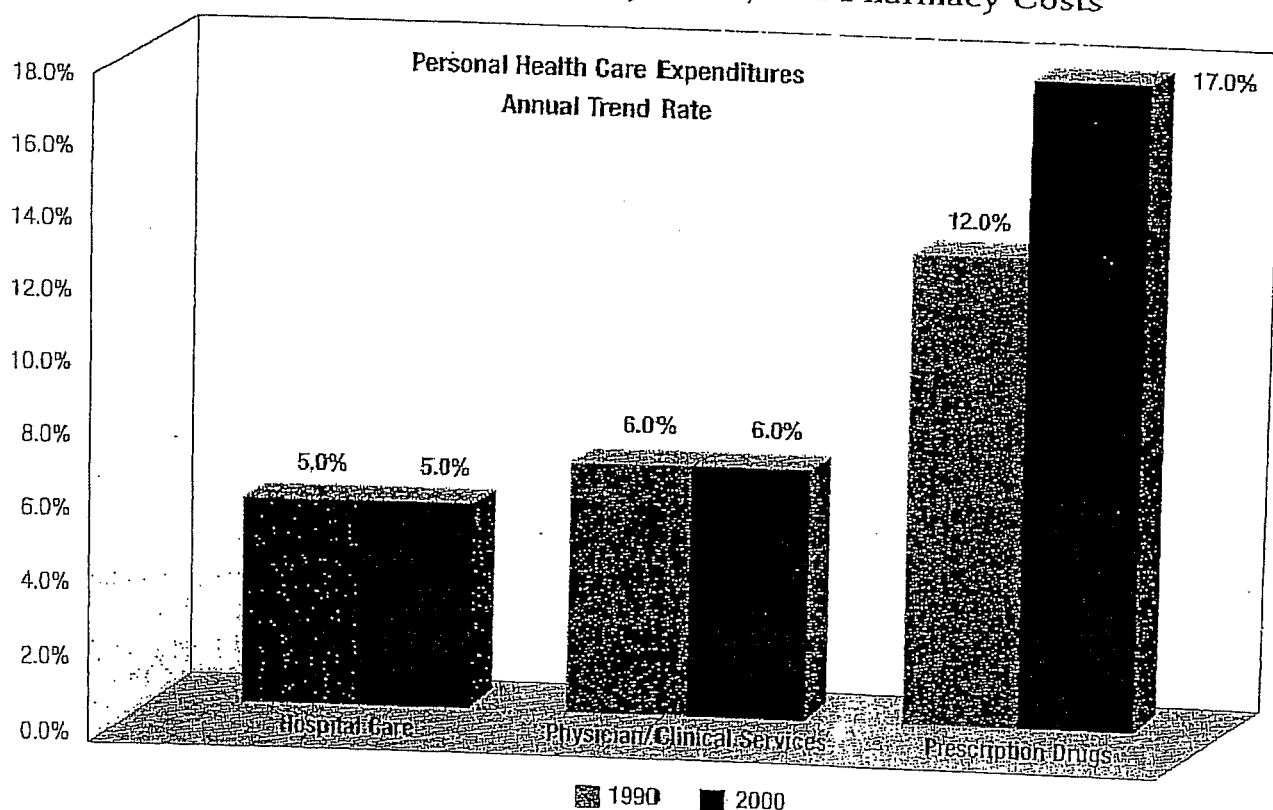
outcomes research in health plans, addressed below, provides the linkage between appropriate use of cost-effective drugs and positive outcomes, and helps administrators and payers shift from cost-minimization to value promotion. To achieve this goal, pharmacy benefit managers attempt to select the most cost-effective drugs for formulary inclusion, implement programs to promote the appropriate use and adherence, and document value by measuring outcomes. These goals are no different than those of hospital pharmacists, but they are more difficult to control as the MCO pharmacy director is often managing prescription benefits for hundreds of thousands of patients with literally every known disease.

Pharmacy Benefit Managers (PBMs)

Many large health plans manage their pharmacy benefit programs through an internal pharmacy department. Even so, the vast majority of health plans also use a

Figure 6-3

Annual Trend Rates for Hospital, Physician, and Pharmacy Costs



Source: Centers for Medicare & Medicare Services, Office of the Actuary, National Health Statistics Group. Available at: <http://www.cms.hhs.gov/review/supp/2001/table4.pdf>.

variety of services offered by pharmacy benefit managers, PBMs, which have evolved as experts in pharmacy benefit management. Pharmacy PBMs are specialized companies that provide managed prescription drug benefits to health plans, government plans (e.g., Medicaid, Medicare), or to self-funded employer groups. PBMs do not offer any services a health plan could not develop through an internal pharmacy department. However, PBMs manage millions of lives, and the economies of scale regarding computer services, patient call centers, contracting with pharmacies and with pharmaceutical manufacturers may make PBM services less costly than if an MCO built their own internal PBM.

The amount of PBM services purchased by MCOs, Medicaid plans, and self-insured employers, depends entirely on the needs of the customer. Some of the offered services include the following:

- Pharmacy distribution network (community, mail, and possibly specialty products)
- Drug formulary development and management, including generic substitution program (maximum allowable cost [MAC] list maintenance)
- P&T Committee services including new drug reviews
- Pharmaceutical manufacturer contracting
- Physician and member communication
- Member service help line
- Provider and member website development and maintenance
- Drug utilization review services (prospective, concurrent, and retrospective)
- Clinical pharmacy services (DUR, adherence monitoring, clinical edit development) and disease management programs
- Claims processing and report generation

Some PBMs are captive, or internal PBMs, of a large health care organization. Most PBMs exist as independent companies (e.g., Medco Health Solutions, AdvancePCS/Caremark, Express Scripts, Inc.), although they may be associated with health plans (e.g., Prescription Solutions PBM, a subsidiary of PacifiCare Health Plans, and WellPoint, now a part of Anthem Health Care), or a component of a retail pharmacy chain (e.g., Walgreens Health Initiatives, CVS PharmaCare). Humana has its own internal PBM that only serves its own commercial members at this time.

However, there has been much consolidation in the PBM market due to mergers, acquisitions, and divestitures. Pharmaceutical companies formerly owned two of the largest PBMs. Merck owned Medco Health Solutions, now an independent company, and SmithKline-Beecham owned DPS, which was borne out of United HealthCare and is now part of Express Scripts, Inc. Table 6-2 provides a list of largest PBMs.

Table 6-2

List of Top PBMs and Membership

Membership of the Largest U.S. Pharmacy Benefit Managers

Caremark/AdvancePCS	105 million
Medco Health Solutions	70 million
Express Scripts, Inc.	53 million
WellPoint	40 million
MedImpact	30 million

Source: R. Navarro, adapted from PBM websites and marketing material, 2005.

Components of a Managed Prescription Drug Benefit Plan

Pharmacists operating health plan pharmacy benefits have borrowed many management strategies from hospital pharmacy programs, including the P&T Committee, the drug formulary, pharmaceutical company contracting, physician education, utilization review, and health outcomes research. However, health plans have had to include additional capabilities, such as development of a community and mail distribution system, member communication and education, and massive computer systems to process millions of claims in a real-time environment.

Certificate of Coverage

Managed care plans do not claim to provide any and all desired health care services. Rather, a payer purchases, and a health plan provides, defined benefits as specified in a state regulated contract (e.g., Certificate of Coverage or other similar name) that is generally renegotiated annually. The contract defines included and excluded benefits, as well as the access rules through which members must obtain benefits. Drugs typically excluded from coverage include the following:

- Experimental or investigational drugs
- Approved drugs when prescribed for unapproved indications (although this is generally unenforceable as community pharmacies generally are not aware of the diagnosis or medication indication; this restriction is usually reserved for expensive drugs or injectables subject to prior authorization, when the drug indication may be verified)
- Drugs used for cosmetic purposes (e.g., Botox for wrinkles) or lifestyle drugs (e.g., PDE-5 inhibitors)
- Brand name drugs for which there are AB-rated generic equivalent that is subject to mandatory generic substitution (e.g., mandatory maximum allowable cost [MAC] program)
- Drug for which there is an identical OTC equivalent, such as ibuprofen 200 mg; insulin is an exception, as it is a nonprescription drug in many states but remains covered by health plans

Health plans use drug formularies to communicate drug coverage as well as member copayment requirements and other restrictions (formularies are discussed below).

Distribution Channels for Outpatient Pharmaceuticals

Managed care organizations must develop a pharmaceutical distribution system that meets member needs for easy access to prescription services as well as containing ingredient and dispensing costs. Closed-model health plans or large employer groups may have in-house, owned pharmacies for member convenience supplemented with community pharmacies, often with mail service. Open-model plans will use a community-based pharmacy including pharmacy chains and independent pharmacies, and often mail service as well. Many pharmacy chains also offer mail service.

Pharmacies participating in the pharmacy provider network agree, by contract, to dispense drugs prescribed by plan physicians to eligible members according to the drug formulary and other benefit design requirements. Pharmacists may participate in many different managed pharmacy programs, and by contract must use the online, real-time point-of-service (POS) computer system to verify coverage information (eligible drug, member, and physician), learn any dispensing limitations or requirements (e.g., quantity limits, step-care protocols), obtain copayment information, and

know the level of reimbursement from the health plan or PBM. Pharmacists received a discounted ingredient cost reimbursement (based on a discount off the AWP) and a dispensing fee. Other payments may exist, such as for a special generic substitution or member clinical consultation.

Specialty Pharmacy Distribution

The increasing use of high cost injectable biotech products that may require special handling has caused the development of many specialty pharmacy distributors (SPDs). Specialty pharmacy services may also be offered by PBMs. SPDs may send injectables directly to a physician office for a patient appointment for drug infusion, or drugs can be mailed directly to a member's home. Volume purchasing by SPDs introduces cost efficiencies into the system that are passed on to payers and members. This system prevents physicians from stocking and storing expensive medications and removes them from the flow of dollars, as the SPD bills the health plan or member directly, and the physician is paid an administration fee by the health plan. The growing availability to biotechnology pharmaceuticals will likely increase the role and importance of SPDs in the future.

Pharmacy and Therapeutics Committee Management

Managed care has borrowed the P&T Committee concept from hospitals as a source for formulary development and drug coverage decisions. In addition to the clinical drug review, the Committee must make recommendations on formulary coverage and copayment tier and other dispensing limitations or restrictions. Managed care P&T Committees typically consist of 10 to 15 physicians and pharmacists and meet quarterly. Clinical pharmacists with the health plan or PBM review available published and manufacturer clinical and economic data, the Academy of Managed Care Pharmacy Format for Formulary Submissions, consider plan-specific expected utilization patterns, other formulary drugs, manufacturer contracts, and present recommendations to the P&T Committee for formulary action. Due to concerns about drug safety and utilization patterns, new drugs are usually not formally reviewed for formulary consideration for at least 3 to 6 months postlaunch. During that time, the drug may be available for reimbursement as a nonformulary or nonpreferred drug, usually on the copayment Tier III.

Clinical data (efficacy/effectiveness and safety) are the primary formulary decision criteria, but net cost is quite high as a decision consideration as well. Increasingly, credible health outcomes and economic data are available and considered by managed care P&T Committees, and formulary decisions are based on clinical, economic, and humanistic outcomes rather than solely on pharmacy budget cost minimization. The AMCP Format for Formulary Submissions in particular provides a standardized method for pharmaceutical companies to submit all relevant clinical and economic information on a drug considered for formulary inclusion. The Format for Formulary Submissions supports the informed selection of pharmaceuticals, biologicals, and vaccines.³

- standardizing and communicating product and supporting program information requirements
- projecting their impact on both the organization and its enrolled patient population
- making evidence and rationale supporting all choice(s) more clear and valuable by decision makers

Drug Formulary Development and Management

Health plans and PBMs have used drug formularies for the same reasons they are used in hospitals—to promote the most cost-effective pharmaceuticals in the most appropriate manner. The benefit design is enforced through the formulary, which is the basis for the drug and reimbursement information used by the pharmacist to process eligible claims using the POS system. Formulary booklets are mailed to participating physicians and often abridged formulary documents are provided to members, although many plans and PBMs provide pharmacy benefit and formulary information for physicians and members online. Formularies are fundamentally a method of communicating drug coverage and reimbursement policies to physicians and patients.

Some formularies are *open*, signifying most drugs are eligible for reimbursement, although the level of member copayment varies with a drug's formulary position and copayment tier. Other formularies may be *closed*, indicating a select number of drugs are eligible for reimbursement, while others are not covered. Some drugs are *on formulary* but available only if the patient satisfies certain prior authorization (PA) criteria. Drugs

may be subject to a PA based on cost or safety issues, to attempt to control use for labeled indications only or for certain types of patients. The open and closed nature of formularies is cyclical. In the recent past, formularies were more inclusive with most nonformulary products covered on Tier III, but due to rising costs many MCOs are returning to more restrictive formularies and continuing higher and tiered copayments.

Physician and member formulary conformance is enforced using different mechanisms depending on if the formulary is inclusive or exclusive. Closed formularies do not allow for reimbursement of nonformulary products, and pharmacists must contact the prescribing physician to request a change for a formulary product, or the patient must pay cash for a nonformulary product. Open formularies use a tier copayment structure, described below, to encourage physician prescribing and member use of generics or preferred formulary products. Physicians are provided copies of formularies and made aware of formulary changes through mail, newsletters, and email. Some health plans and PBMs employ pharmacists for academic detailing of physicians who continuously disregard the formulary. Many health plans and PBMs provide physicians *formulary conformance report cards* and indicate opportunities for prescribing changes that favor formulary products. Some plans and PBMs offer financial incentives to physicians for high levels of formulary conformance.

Health plans, PBMs, and employer groups often used a tiered formulary structure to apply the member copayment to share costs with utilizing members, and to influence physician prescribing and member acceptance of lower cost drugs when appropriate. There are typically two copayment tier plans, but more plans are adopting three or more copayment tier plans.

Copayment Tier I generically contains generic drugs, and due to the lower generic cost the member copayment is lower to encourage use of generics. *Copayment Tier II* is reserved for preferred or formulary products, and a medium-level copayment amount is assigned. These are generally branded drugs and are more expensive than generics but considered necessary medications. *Copayment Tier III* products are nonformulary or nonpreferred brand drugs, placed on a higher tier due to high cost or because there are cost-effective options on Tier II. Some plans include Tier IV for lifestyle, cosmetic medications, or injectables. The dollar amounts of the various tiers are increasing, as is the delta between tier amounts. Table 6-3 provides

examples of a tiered formulary for the HMG Co reductase category.

Critics of high dollar copayments claim the increasing copayment amounts are financial deterrents to members obtaining and remaining on prescribed drugs.

Table 6-3
Example of Statin Formulary
Copayment Tiers

Tier I	Tier II	Tier III
Generic	Preferred Formulary Brand	Nonpreferred or Nonformulary Brand
Lovastatin	Lipitor (atorvastatin) Pravachol (pravastatin)	Crestor (rosuvastatin) Leschol (fluvastatin) Zocor (simvastatin)
\$12.00	\$25.00	\$45.00

Source: R. Navarro, 2005.

Research is controversial on the matter and can be criticized by ignoring the numerous other factors that influence drug adherence, such as lack of understanding, forgetfulness, belief that medications are unnecessary, adverse effects, and cultural barriers to medications.

Pharmaceutical Manufacturers Contracts

As hospitals contract for drugs with GPOs and manufacturers, health plans and PBMs similarly negotiated discounts or rebate for selected drugs in exchange for a favorable formulary position. Savings obtained reduce the net price of contracted drugs, and the savings are passed on to customers. Rebates (the favored contract for health plans and PBMs who do not take possession of drugs) generally include an access rebate as well as a performance rebate based on achieving certain market share or volume goals.

Clinical Pharmacy Services

Health plans and PBMs offer an array of clinical pharmacy services, many of which are online and real-time edits provided to the dispensing pharmacist. Others include prospective or retrospective utilization monitoring, adherence intervention, and disease management programs.

Online, real-time point-of-dispensing edits provide commonly used guidance regarding drug interactions, early refill prevention, duplicate medications, age and gender edits, and step-care edits. Health plans and PBMs also provide computerized DUR, screening for drug misuse and abuse, polypharmacy, nonadherence, and other dangerous or inappropriate drug use patterns. Interventions may include patient and or physician communications requesting clarification of the potential dangerous pattern.

Health plans may offer disease-specific management programs to augment health care services provided by plan physicians, which may provide general disease education, diagnostic screening events (e.g., hypertension, diabetes, or dyslipidemia screening), and case management for high-cost and high-risk conditions (e.g., CHF, diabetes, asthma). Pharmaceutical manufacturers may provide some unbranded disease management resources (e.g., physician or patient education) to supplement health plan efforts,

Quality Initiatives

In addition to helping customers manage rapidly rising health care costs, health plans must provide high quality health care delivery services. The National Committee for Quality Assurance (NCQA) is a private, not-for-profit organization dedicated to improving health care quality and provides many mechanisms and reports on quality of care provided by health plans, physicians, disease management providers, and managed behavioral health organizations. NCQA publishes the Health Plan Employer Data and Information Set, or HEDIS measures, which are tools used by health plans to measure performance on important dimensions of care and service. Many employer groups consider NCQA accreditation and HEDIS measure scores to reliably compare the performance of managed health care plans when selecting health plans for their employees.

NCQA 2004 HEDIS measures consist of 60 measures to assess Access/Availability of Care, Satisfaction with the Experience of Care, Health Plan Stability, Use of Services, Health Plan Descriptive Information, and 22 Clinical Effectiveness measures. The Clinical Effectiveness measures that involve the use of pharmaceuticals include the following:

- Childhood and adolescent immunization status
- Appropriate treatment for children with upper respiratory infection

- Osteoporosis management in women who had a fracture
- Beta blocker treatment after a heart attack
- Cholesterol management after acute cardiovascular event
- Use of appropriate medications for people with asthma
- Antidepressant medication management
- Flu shots for adults
- Management of urinary incontinence in older adults

Assuring the appropriate use of cost-effective pharmaceuticals is an important responsibility for pharmacy directors of managed care organizations. The growing use of HEDIS measures that include drug use help employer groups recognize that pharmacy benefits are not merely a cost center but a source of overall clinical and economic value.

Electronic Prescribing

The rapid expansion of information technology applications in health care presents novel opportunities and challenges for pharmacists. Although electronic prescribing is not widespread and still in a pilot phase, many MCOs are experimenting with electronic data transfer of prescription-related information among trading partners: the health plan, physician, and pharmacy. Electronic prescribing refers to the use of computing devices to enter, modify, review, and output or communicate drug prescriptions.⁴ In inpatient care, electronic medication ordering increases prescribing accuracy, dispensing efficiency, and reduces the number of adverse drug events and redundant medications. A number of outpatient pilot projects and initiatives in electronic prescribing are proliferating within managed care organizations to achieve the same goals and are also providing medication history, drug formulary options, drug hypersensitivities, and other clinically relevant data to the prescriber at the point of prescribing.

In the ambulatory environment, recent research shows that adverse events are common and can be serious. The Center for Information Technology Leadership reports that more than 8.8 million adverse drug events occur each year in ambulatory care, of which over 3 million are preventable, many resulting in deaths.⁵ In addition to reducing adverse drug effects, electronic prescribing can improve quality,

efficiency, and reduce costs through other benefits, including the following⁶:

- Actively promoting appropriate drug usage
- Providing information about formulary options and copay information
- Improving dispensing efficiency and accuracy by providing instant electronic connectivity between the physician, pharmacy, health plans, and PBMs

More than 3 billion prescriptions are written annually.⁷ Given this volume, even a small improvement in quality attributable to electronic prescribing would translate into significant health care cost and safety benefits if electronic prescribing is broadly adopted. Studies suggest that the national savings from universal adoption of electronic prescribing systems could be as high as \$27 billion, including \$4 per member per year savings from preventable adverse drug events and \$35–\$70 per member per year savings from more appropriate use of medications, for a total savings of \$39–\$74 per member per year.⁸ Electronic prescribing has significant benefits for pharmacists as well. The Institute for Safe Medication Practices estimates that pharmacists spend a significant amount of their time each day clarifying prescription orders and making 150 million phone calls to physicians annually on prescription accuracy-related issues.⁹

PBMs have taken a leadership role in developing and promoting electronic prescribing initiatives. The three largest PBMs—AdvancePCS, Express Scripts, and Medco Health Solutions—sponsored the development of RxHub in 2001 to create a single point of communication of information related to accurate and cost-effective prescription prescribing and dispensing.¹⁰

Professional Opportunities for Pharmacists in Managed Care

Prescription drugs are the most commonly used health plan benefit and the third largest health care delivery component expenditure, behind inpatient and outpatient physician costs. As a result, cost-efficient pharmacy programs developed and managed by pharmacists are critical to the successful overall operation of a health plan. Many professional opportunities exist for pharmacists within managed care in an overall health plan administration, pharmacy program manager, information technology, provider services, member education, clinical pharmacy services, dispensing activities, and disease management. Specific pharmacy program

activities include the following areas of practice:

- *Pharmacy Benefit Management*—Developing and managing the overall pharmacy benefit, health plan business development, staff hiring and development, pharmacy benefit design development, and marketing benefits to prospective customers
- *Pharmaceutical Manufacturer Contracting*—Negotiating and administering discount contracts with drug companies
- *Pharmacy Network Management*—Negotiating contracts with community and mail service pharmacies, and specialty pharmacy distributors
- *Clinical Pharmacy Services*—Developing and executing clinical programs, including utilization review, online clinical edits, adherence interventions, physician and patient education, and disease management programs
- *P&T Committee and Formulary Management*—New drug clinical and economic data review, development of clinical monographs, evaluation of AMCP-compliant formulary guideline submissions from manufacturers, P&T Committee membership, and academic detailing of physicians
- *Health Outcomes Research*—Economic research, pharmacy benefit design impact research, research result publishing, and support of P&T Committee activities related to drug economic evaluations
- *Information Technology*—Pharmacy computer system development, health plan website development, performance report generation, and interface with electronic prescribing and data interchange trading partners

Numerous professional clinical and business opportunities exist for pharmacists, with more positions developing every year as managed care expands and broadens its service offerings. Outside of health plans and PBMs but within managed care, pharmacists have unlimited entrepreneurial opportunities in related companies and activities including disease management, specialty pharmacy, information technology, health education, and health outcomes research.

Evolution of Health Care Management

Health care in the U.S. is a market driven business.

Commercial and government payers have many choices when selecting health plans. PBMs, and other vendors and customizing health, pharmacy, and ancillary benefits for their members. We have seen a continuous evolution of managed care organizations and benefit design driven in concert by health plans (attempting to develop novel health care benefits with richer benefits yet at a competitive price) and payers who make demands on the market and offer their business to health plans and PBMs that best satisfy their unique cost and quality demands.

While there are many trends within managed care, perhaps the following will have the greatest impact on pharmacy benefit management in the coming years.

Continuing Pressure on Health Plans and PBMs to Contain Costs

This will result in higher member prescription copayments and greater number of employers adopting a tiered copayment structure. Approximately 75% of commercial managed care lives are now subject to a three-tier copayment structure today, and this will increase as payers attempt to contain and shift costs to utilizing members. Opponents claim that higher copayments will present financial barriers for some members, and may result in nonadherence of prescriptions. Several high cost, high utilization drugs will lose patent protection over the next few years, which will provide opportunities for pharmacy benefit cost savings. This is balanced by the increasing availability of expensive biotechnology products that, for some patients, provide outcomes not realized with existing medications, but at a higher cost.

Lower Member Drug Copayments for Specific Diseases

In contrast to the above trend, there is emerging interest by some employers groups, such as Pitney-Bowes, to reduce the prescription copayment for cost-effective drugs to treat several high cost and high prevalence medical conditions, including diabetes, asthma, CHF, and dyslipidemia. The market is curious and cautiously watching the impact on drug adherence and, more importantly, medical and economic outcomes of these benefit design changes.

Availability and Acceptance of Health Savings Accounts (HSAs)

These novel mechanisms, actually tax-deferred medical savings accounts, allow members to save and spend a

fixed amount of tax-deferred dollars for an array of customized health benefits. For example, members (or their dependents) who use several high-cost drugs may allocate a greater portion of their personal HSA for pharmacy benefits to minimize their out-of-pocket spending. HSAs can be confusing for members but when understood are likely to be quite popular and will give the member more freedom of choice. This presents opportunities for pharmacists to counsel their patients on the most cost-effective drug use.

Growth in the Acceptance of Health

Outcomes Data

Over the past 20 years, managed care has evolved from managing health care components (e.g., hospital, physician, pharmacy benefits) in isolation without evaluating the impact of the appropriate use of cost-effective drugs on reducing hospitalizations, diagnosis tests, and physician visits. Partially due to the AMCP Format for Formulary Submissions and published health outcomes data, P&T Committees are selecting formulary products with overall value in total direct medical cost containment and quality of life. Payers, unfamiliar with health outcomes methodologies, have traditionally encouraged cost-minimization in pharmacy benefit management and are beginning to understand the impact of cost-effective drugs in member (employee) quality of life, absenteeism, and productivity. As a result, enlightened payers are focusing on direct, as well as indirect, health outcomes and encouraging health plans and PBMs to provide adherence intervention.

Medicare Modernization Act of 2003

The most sweeping changes in Medicare since its inception were signed into law by President Bush in December 2003. The Medicare Modernization Act (MMA) adds outpatient prescription drug benefits for 41 million Medicare recipients beginning in January 2006 under Medicare Part D. The MMA also makes important changes in reimbursement of injectable drugs currently covered through Medicare Part B. The Congressional Budget Office predicts 87% of eligible Medicare recipients will enroll to receive outpatient medical and pharmacy benefits through Medicare Advantage (MA) provider (formerly Medicare+Choice plans) or pharmacy benefits alone from a Prescription Drug Program (PDP) provider. MA plans must be a health plan or insurer, but PDPs may be MA plans (called MA-PDP) or PBMs (PDP). Current Medicaid

dual eligible beneficiaries will be auto-enrolled into a Medicare provider to obtain pharmacy benefits. At this writing, many regulations and policies remain undecided, but the final benefits, formulary guidance, reimbursement levels, and selected health plans and PDPs will be determined throughout 2005.

Electronic Prescribing

As described above, electronic prescribing will increase as pilot programs are successful and demonstrate cost efficiencies and improve the quality of care. Dispensing pharmacists will likely realize time savings and obtain more drug history and clinical information to allow a more meaningful interaction with the patient. If these objectives are realized, electronic prescribing may provide further support of pharmacist reimbursement for pharmacotherapy management counseling.

Transition from Managing Costs to Care Management

We have described the development, management, and future trends of managed care pharmacy benefits. In the 31 years since the HMO Act was signed into law, managed care has grown to be the primary method of financing and delivery health care in the U.S., although managed care organizations are quite diverse in how they meet customer expectations.

Managed care has continuously evolved since its inception, although the fundamental tenets on which managed care was founded remain the same—delivery of cost-effective and high quality health care with an emphasis on preventive medicine. The role of pharmacy benefit management has evolved from being a cost center to a source of significant value, contributing to clinical, economic, and humanistic outcomes. The transition from managing costs to managing care through appropriate use of cost-effective pharmaceuticals is largely the result of health outcomes data demonstrating the link between pharmaceutical use and health outcomes.

Managed care has presented many opportunities for pharmacists in population-based pharmacy benefit management, health outcomes research, and entrepreneurial adventures. The future indicates even greater opportunities will be present for pharmacists to demonstrate the value of medicines as well as the profession of pharmacy.

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